K092171

Exhibit 5 510(k) Summary

Digital Extraoral Source X-Ray System / Model: VOLUX

APR 2 6 2010

1. Submitter and US Official Correspondent

Submitter:	GENORAY Co., Ltd.
Address:	#512, Byucksan Technopia
	434-6, Sangdaewon 1-dong,
	Jungwon-gu, Seongnam-city
	Gyeonggi-do, 462-716, Korea
Telephone No.:	+82-31-737-8020
Fax:	+82-31-737-8025

Official Correspondent (U.S): Jae Kim - Business Manager

Correspondent :	GENORAY America Inc.
Address:	1073 N. Batavia St.
	Orange, CA 92867, USA
Telephone No.:	714-289-8020
Fax:	714-453-9661
Email:	jae@genoray.com

2. Establishment Registration Number

3005843418

3. Device Information

Proprietary/Trade Name:	Digital Extraoral Source X-Ray System / Model: VOLUX
Common/Usual Name:	Digital Extraoral Source X-Ray System
Classification Name:	System , X-ray, Extraoral Source, Digital
Product Code:	MUH
Device Class:	Class II per regulation 21 CFR 872.1800

4. Equivalent Legally Marketed Device

< CB MercuRay >

Manufacturer:	Hitachi Medical Systems America, Inc.
Device Name:	CB MercuRay
510(k) Number:	K033248 (Decision Date – October 20, 2003)
Classification:	System, X-Ray, Extraoral Source, Digital : MUH,
	Class II per regulation 21 CFR 872.1800

< Galileos >

Manufacturer:	Sirona Dental Systems GmbH .
Device Name:	Galileos
510(k) Number:	K060892 (Decision Date – April 14, 2006)
Classification:	System, X-Ray, Extraoral Source, Digital : MUH, Class II per regulation 21 CFR 872.1800

5. Description of the Device

The VOLUX comprises of the VOLUX-device, the reconstruction server and the 2D and 3D viewing client TRIANA. The VOLUX device generates a conical x-ray beam that rotates round the patient's head within a certain angle. From the obtained exposures a three dimensional image is reconstructed and can be viewed. The VOLUX features the navigation within this displayed volume and special views may be selected, calculated and eventually displayed.

Product / Items	VOLUX
kV range	60~85kV
mA range	5~7mA
mAs range	30~42mAs
X-ray Source Mode	Pulse mode
Image Detector	Image Intensifier
Voxel Size	6" : 0.1667mm 4" : 0.1111mm
Camera Pixel	1004(H) x 1004(V)
Image Acquistion	220°
Exposure time	10sec
Scan time	20sec
Image reconstruction time	3 min
Reconstruction type	Cone beam
Focal spot size (small)	0.5mm
Total filtration	2.8mm Al equivalent (inherent filtration 0.8mmAl)
Source to skin distance	200mm
Main unit Dimensions (mm)	1500 X 1750 X 1950
Total weight	220kg

6. Indications for use

The VOLUX consists of an x-ray device that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume reconstructions of the head area, which includes dental and maxillofacial areas, for use in planning and diagnostic support.
VOLUX comprises a package of PC software modules to expand TRIANA capabilities to handling 3D data. This includes 3D reconstructions, storage, retrieval, viewing and processing of 3D-image data.

7. Safety and Effectiveness, comparison to Predicate

The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

APR 2 6 2010

GENORAY Co., Ltd.
% Mr. Jae Kim
Business Development Manager
GENORAY America, Inc.
1073 N. Batavia St.
ORANGE CA 92867

Re: K092171
Trade/Device Name: Digital Extraoral Source X-Ray System (Models: VOLUX)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: March 23, 2010
Received: March 24, 2010

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Exhibit 4 Indications for use

510(k) number (if known): K092171

Device Name: Digital Extraoral Source X-Ray System (Models: VOLUX)

Indications for Use:

The VOLUX consists of an x-ray device that uses a cone beam with a rotational sequence, providing two dimensional images and three dimensional volume reconstructions of the head area, which includes dental and maxillofacial areas, for use in planning and diagnostic support.
VOLUX comprises a package of PC software modules to expand TRIANA capabilities to handling 3D data. This includes 3D reconstructions, storage, retrieval, viewing and processing of 3D-image data.

Prescription Use ___V___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation~~ (ODE) OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K092171